JOHN W. HUBER, United States Attorney (#7226)
MICHAEL GADD, Special Assistant United States Attorney (#13704)
VERNON G. STEJSKAL, Assistant United States Attorney (#8434)
KENT A. BURGGRAAF, Special Assistant United States Attorney (#13044)
Attorneys for the United States of America
111 South Main Street, Suite 1800
Salt Lake City, Utah 84111
Telephone: (801) 524-5682
Email: michael.gadd@usdoj.gov

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. AARON MICHAEL SHAMO, Defendant.	Case No. 2:16-cr-631DAK NOTICE RELATING TO EXPERT TESTIMONY PURSUANT TO Fed.R.Crim.Pro. 16(a)(1)(G) AND Fed.R.Evid. 702 Judge Dale A. Kimball

The United States of America, by and through Special Assistant United States Attorney Michael Gadd, and pursuant to Rule 16(a)(1)(G) of the Federal Rules of Criminal Procedure and Rule 702 of the Federal Rules of Evidence, hereby provides to the defendant the following notice relating expert testimony the United States may offer in the trial of this case. The United States hereby offers this notice regarding the potential expert testimony of Dr. Arthur F. Simone, M.D, Ph.D., of the Food and Drug Administration (FDA). The summary of the testimony of this witness and the basis for his testimony are listed below.

A. **Rule 16(a)(1)(G) Summary**: Dr. Simone may offer expert testimony on the following subjects:

Fentanyl and Oxycodone. Dr. Simone will offer detailed expert testimony about the Schedule II Controlled Substance Fentanyl. Dr. Simone will testify that Fentanyl is a drug, as defined by 21 U.S.C. 321(g)(1), and is an opioid drug that is regulated by the laws of the United States. Dr. Simone will offer detailed expert testimony about the Schedule II Controlled Substance Oxycodone. Dr. Simone will testify that Oxycodone is a drug, as defined by 21 U.S.C. 321(g)(1), and is an opioid drug that is regulated by the laws of the United States. He will testify that Oxycodone is listed in the Official US Pharmacopeia Compendium. He will testify that legitimate tablets marked "A 215" are manufactured and distributed by Actavis and contain oxycodone, but do not contain fentanyl. He will testify that legitimate tablets marked "M" on one side and "30" on the other are manufactured by Mallinckrodt Pharmaceuticals and contain oxycodone but do not contain fentanyl. He will testify as to the potency of both fentanyl and oxycodone, as compared to other opiates. He will testify as to the effect these substances have on the human body. He will testify that putting fentanyl in a tablet displaying markings for oxycodone tablets has a reasonable probability of causing adverse health consequences or death if consumed by humans. He will testify in further detail with regard to each of these matters.

Misbranding. Dr. Simone will discuss whether the FDA has ever approved the products the defendant manufactured, held for sale, and/or sold. He will discuss what the FDA generally expects to see on the label of an FDA-compliant drug, including, but not limited to, truthful and accurate statements, the name and address of the manufacturer, packer, or distributor, the established name of active ingredients, adequate directions for use, and adequate warnings. Dr. Simone will offer the opinion that the products the defendant manufactured, held for sale, and/or sold were misbranded drugs. He will testify that the drugs the defendant manufactured, held for sale, and/or sold were misbranded because the label and labeling was false or misleading because

of affirmative statements and material omissions. He will testify that the drugs the defendant manufactured, held for sale, and/or sold were misbranded because the label did not bear the name and place of business of the manufacturer, packer, or distributor. He will testify that the drugs the defendant manufactured, held for sale, and/or sold were misbranded because the label did not contain an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. He will testify that the drugs the defendant manufactured, held for sale, and/or sold were misbranded because the label did not bear the established name of each active ingredient. He will testify that the drugs the defendant manufactured, held for sale, and/or sold were misbranded because the label did not bear adequate directions for use. He will testify that when a manufacturer or distributor of a drug claims to not know the ingredients of the drug manufactured and distributed, and cannot identify the ingredients of the drug, or cannot attest to the accuracy of the ingredients listed on any label for the drug, it is impossible for the manufacturer or distributor to comply with the FDA's labeling requirements, thus making the drug misbranded. Dr. Simone will further testify that when a manufacturer or distributor of a drug knows the ingredients of a drug, but fails to list the ingredients on the label, the label will be false and misleading, and the drug will be misbranded.

B. **Expert Qualifications**: Rule 702 of the Federal Rules of Evidence provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.[1]

1 FRE 702.

A copy of Dr. Simone's curriculum vitae (CV) is attached as Attachment A. This document establishes his qualification to testify with regard to the above-described matters. Dr. Simone will testify in detail with regard to his education, training, and experience in this area.

RESPECTFULLY SUBMITTED this 26th day of November, 2018.

JOHN W. HUBER
United States Attorney

/s/Michael Gadd
MICHAEL GADD
Special Assistant United States Attorney